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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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DAVID W. LYNCH
CRAWFORD MAUNU PLLC
1270 NORTHLAND DRIVE
SUITE 390
MENDOTA HEIGHTS, MN 55120

EXAMINER	
JOHNSTON, PHILLIP A	
ART UNIT	**PAPER NUMBER**
2881	

DATE MAILED: 11/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	Application No.	Applicant(s)
	10/077,036	PARKER ET AL.
	Examiner	Art Unit
	Phillip A Johnston	2881

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *70-147* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *70-147* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 February 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____.

Detailed Action

1. This Office Action is submitted in response to Amendment dated 8-14-2004, wherein claims 70-147 are pending.

Claims Rejection – 35 U.S.C. 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 70-88,105-127, and 145-147 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2002/0059047 to Haaland, in view of Obremski, U.S. Patent No. 5,498,875.

Regarding Claims 70-73, Haaland (047) discloses an algorithm for predicting analyte concentration that accommodates system spectral drift that includes;

(a) A method of multivariate spectral analysis of repeat (sequential) sample spectra, where the repeat spectral shapes are transformed into a matrix of row vectors from which time dependent (an independent variable, as recited in claims 70,73, and 145) spectrometer drift spectral data are subtracted, resulting in a drift compensated

matrix; i.e., compensated for the effects of drift as related to the independent variable time, as recited in Claim 70. See paragraphs [0026] and [0031].

(b) Performing a factor analysis that includes eigen vector analysis of mean centered temporal drift spectra, resulting in a set of principal factors, compensated for the effects of drift as related to the independent variable time, as recited in claims 70, and 145. See paragraphs [0004] and [0031].

(c) Generating a prediction curve from matrixed spectral shape data (profile trajectories) that has been compensated for the temporal spectral drift of the spectrometer, as recited in claims 70 and 145. See paragraph [0066] and Figure 12.

Regarding Claims 105-109,111, and 112, Haaland (047) also discloses the use of a Nicolet 800 Fourier Transform spectrometer. See paragraph [0048]. Haaland (047) further discloses that the algorithm can be applied to other types of spectroscopy, as recited in claims 106-109. See paragraph [0027].

Haaland (047) as applied above fails to teach the use of software (programs of instructions executable by a computer), as recited in claims 145-147. However, Obremski (875) discloses a number of available spectral analysis software packages. See Column 10, line 5-19.

Therefore it would have been obvious to one of ordinary skill in the art that the multivariate spectral analysis apparatus and method of Haaland (047) can be modified to use the software packages of Obremski (875), to provide the ability to process arrays and vectors representative of the data, resulting in the quantitative measurement of properties of unknown samples.

The combination of Haaland (047) in view of Obremski (875) discloses the claimed invention except for the spectral analytical techniques recited in Claims 74-88,110, and 113-127. However Obremski (875) teaches in Column 10, line 5-19 that spectral analysis procedures are well known, and are described, for example, in Factor Analysis & Chemistry by Malinowski and Howery (Wiley-Interscience 1980) as does Haaland (047) in paragraphs [0004] and [0042].

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention was made to utilize the spectral analysis procedures as taught by Obremski (875) and Haaland (047), and that such modification would provide the ability to process arrays and vectors representative of the spectral data, as recited in claims 74-88,110, and 113-127.

4. Claims 89-104, and 128-144 stand rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Pub. No. 2002/0059047 to Haaland, in view of Obremski, U.S. Patent No. 5,498,875, and in further view of Ito, U.S. Patent No. 6,393,368.

Haaland (047) in view of Obremski (875) as applied above fails to teach the use of phase shift analysis in waveform processing, as recited in claims 145-147. However, Ito (368) discloses waveform factor analysis along the time axis. See Column 2, line 47-65; and Column 4, line 58-65.

Therefore it would have been obvious to one of ordinary skill in the art that the multivariate spectral analysis apparatus and method of Haaland (047) in view of Obremski (875) can be modified to use the waveform factor analysis apparatus and

method of Ito (368), to provide methods and apparatuses for analyzing spectra and to provide information useful in analyzing the components of a sample.

Examiners Response to Arguments

5. Applicant's arguments filed 8-14-2004 have been fully considered but they are not persuasive.

Argument 1.

Applicant states that "Applicants respectfully traverse the § 103(a) rejection. Haaland, Obremski and Ito, alone or in combination, fail to disclose, teach or suggest all of the limitations recited in the claims of Applicants application. As will be described below, Applicants' invention is distinguishable from. Haaland, Obremski and Ito, alone or in combination, for several reasons."

Applicant also states that " Because spectral data is required to be related to parameters of interest, no independent variable is present in Halland's hybrid method. Therefore, Haaland does not disclose, teach or suggest transforming a plurality of sequential spectra obtained from a spectrometer to provide an array of row vectors compensated for effects of drift of data along an independent variable axis."

The Office Action erroneously asserts that Haaland discloses " a method of multivariate spectral analysis of repeat (sequential) sample spectra, where the repeat spectral shapes are transformed into a matrix of row vectors from which time

dependent (an independent variable, as recited in claims 70, 73, and 145) spectrometer drift spectral data are subtracted, resulting in a drift compensated matrix; i.e., compensated for the effects of drift as related to the independent variable time, as recited in claim 70. See paragraph [0026]."

Haaland does not discuss transforming repeat sample spectra into a matrix of row vectors from which time dependent spectrometer drift spectral data are subtracted in paragraph 0026. Haaland does mention time in paragraph 0031 where Haaland states, "required spectral shapes can be determined through the use of repeat samples. The best single repeat sample is generally the sample representing the center of the calibration space. In the case of a single repeat sample, the sample spectrum of the repeat sample can be obtained during the period of the calibration. This repeat sample can then represent all the environmental changes occurring during the calibration as reflected by the mid-level sample. "

Haaland uses a repeat sample taken during calibration in order to represent the center of the calibration space, thereby removing time (an asserted independent variable) as a factor. Haaland does not use time as a factor in obtaining spectra, therefore no time axis is present. Thus, Haaland's spectral shape varies only in the y (or dependent variable) axis. Because Haaland does not suggest transforming a plurality of sequential spectra obtained from a spectrometer to provide an array of row vectors compensated for effects of drift of data along an independent variable axis" Haaland cannot account and adjust for spectra data drift of data along the independent

variable axis, which may, for example, result from charging of underlying layers of the structure being analyzed via the spectrometer."

The applicant is respectfully directed to Haaland (047), paragraph [0031], which states; If spectral shapes are due to spectrometer drift, temperature changes, purge gas changes, sample insertion effects, diffraction effects, or other sources of spectral change that are not due to the chemical components in the system, then the required spectral shapes can be determined through the use of repeat samples. The best single repeat sample is generally the sample representing the center of the calibration space. In the case of a single repeat sample, the sample spectrum of the repeat sample can be obtained during the period of the calibration. This repeat sample can then represent all the environmental changes occurring during the calibration as reflected by the mid-level sample. It is known that the drift of the spectrometer looks different on different samples. Therefore, a sample that represents the calibration data is the preferred sample to use. If the sample is invariant with time, then any change in the sample spectrum will represent spectral shapes that generally have not been explicitly included in the CLS calibration. The addition of these spectral changes to the CLS calibration model will compensate for their detrimental influence on predictions. Often it is best to perform an eigenvector analysis (see C. L. Lawson and R. J. Hanson, "Solving Least Squares Problems," Prentice-Hall, Englewood Cliffs, N.J. (1974)) on the repeat sample spectra and to add only those eigenvector shapes that are detrimental to the CLS calibration. In this manner, the detrimental effects of noise on the analysis can be minimized. In addition, it is preferable to perturb the system with

all parameters that are known or suspected of influencing the sample spectra. In this manner, the influence of spectrometer/system changes can be systematically included in the PACLS analysis. It is preferred that these perturbations be performed in a statistically designed manner such as a factorial or fractional factorial design. Examples of changes for infrared and near infrared spectrometers that can be included in the perturbation are system temperature, rate of temperature change, sample temperature, sample insertion effects, source changes (intensity, lifetime, bulb changes, etc.), purge gas composition, alignment changes, etc. In addition, if the spectral changes between calibration sample spectra are large; it may be desirable to also take repeat spectra of other samples in the calibration, e.g., samples at the extreme levels of the calibration design. These repeat sample spectra should be mean centered by sample. After mean centering, the spectra can be combined, and if desired, an eigenvector analysis can be performed on all mean-centered spectra in order to select only those eigenvectors that are important for reducing errors in the CLS analysis. This procedure minimizes the effects of spectral noise from the added spectral shapes. For infrared spectra of dilute solutions, a repeat sample representing the absorbing solvent (e.g., water) can be used for the repeat sample if a calibration sample or other representative sample is not available for repeat measurements. Finally, the correction of the model for spectrometer/system drift can be obtained by collecting the repeat sample spectrum during true CLS prediction of unknown samples. The spectral shape of the difference of the repeat sample spectrum obtained during CLS calibration and prediction can be generated from the spectral

difference of these repeat sample spectra. Again, if multiple repeat spectra are obtained or if multiple repeat samples are used for monitoring spectral drift of the system, then mean-centered differences and eigenvector analysis can be employed to generate the shapes added during CLS predictions. Repeat spectra taken as close as possible in time to the unknown sample spectrum should provide the best correction for drift of the system.

Also paragraph [0053], which states; A further improvement in analysis precision can be realized if the detrimental effects of spectrometer drift during the collection of the unknown samples can be included in the PACLS/PLS analysis. An improvement in prediction ability can be realized by the use of a subset of sample spectra obtained on the spectrometer during both the constant and variable temperature experiments. A subset of 5 samples representing the center-point and extreme samples in the concentration calibration space were removed from the variable temperature data set along with repeat measurement spectra of some of these same samples. The spectra were then used in a CLS calibration to estimate the 6 pure-component spectra of the analytes (i.e., urea, creatinine, and NaCl), plus the solvent, temperature, and linear spectrometer drift. In addition to the concentrations of chemical species, run order was included in the CLS calibration to approximate the linear effects of instrument drift. Since the spectra were obtained at approximately constant time intervals, run order represents time of sample collection. Also, the drift of the system was relatively monotonic with time, so this procedure compensates for some of the detrimental effects of system drift on the CLS calibration. All these pure-component spectra

include at least a portion of the effects of spectrometer drift between the constant and variable temperature experiments.

As well as, paragraph [0057], which states; [0057] If the PACLS/PLS model is allowed to incorporate spectrometer/sensor drift effects occurring after collection of the calibration data and during the collection of the unknown sample spectra, we might expect that the model could maintain a calibration in the presence of significant instrument drift. The spectral shapes of spectrometer/sensor drift can be represented with the use of the center-point repeat sample spectra collected throughout this study. <u>If the repeat sample is truly invariant over time, then the variations in the spectra must represent the spectral variations of spectrometer/sensor drift or spectral effects of insertion variation of the sensor into the spectrometer and the reintroduction of the sample onto the sensor</u>. All the repeat spectra are mean-centered (i.e., the average of the repeat spectra was subtracted from each repeat sample spectrum) to generate the spectral shapes representing spectrometer/sensor drift and sample insertion variation.

The examiner has interpreted from the Haaland (047) references above that Haaland (0470 clearly utilizes repeat sampling with known parameters as independent variables to define spectral shapes representative of the effects of those independent variables, which are stored in a calibration data base and later utilized in a multivariate analysis of unknown spectra, that has been designed to compensate for drift. Calibration spectral shapes were determined for numerous independent variables including; temperature, purge gas changes, sample insertion effects, diffraction effects, chemical composition and time.

Argument 2.

The applicant states "Moreover, Applicants respectfully traverse the Section 103(a) rejection based on Haaland in view of Obremski and in further view of Ito because the Office Action fails to present any evidence that one skilled in the art Would be motivated to combine the cited Haaland, Obremski and Ito references. A Section 103(a) rejection can only be established by combining cited references to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See, MPEP § 2143.01. The Office Action alleges various teachings in the Haaland, Obremski and Ito references without citing any evidence in the Haaland, Obremski or Ito reference that one skilled in the art would combine the alleged teachings to achieve Applicant's claimed invention. Absent any support, the Office Action expresses the conclusory opinion that the references are combinable."

In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that references cannot be arbitrarily combined and that there must be some reason why one skilled in the art would be motivated to make the proposed combination of primary and secondary references. In re Nomiya, 184 USPQ 607 (CCPA 1975). However, there is no requirement that a motivation to make the modification be expressly articulated. The test for combining references is what the combination of disclosures taken as a whole would suggest to one of ordinary skill in the art. In re McLaughlin, 170 USPQ 209 (CCPA 1971) references are

evaluated by what they suggest to one versed in the art, rather than by their specific disclosures.

Conclusion

6. The Amendment filed on 8-14-2004 under 37 CFR 1.131 has been considered but is ineffective to overcome the Haaland (047), Obremski, (875), and Ito (368) references.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications should be directed to Phillip Johnston whose telephone number is (571) 272-2475. The examiner can normally be reached on Monday-Friday from 7:30 am to 4:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiners supervisor John Lee

can be reached at (571) 272-2477. The fax phone number for the organization where the application or proceeding is assigned is 703 872 9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

PJ
November 16, 2004

JOHN R. LEE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 2800